K111290

WOODPECKER

桂林市啄木鸟医疗器械有限公司
GUILIN WOODPECKER Medical Instrument Co.,LTD.

NOV 18 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 4, 2011

1. Company:

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Fax- 541-376-5063
Contact- Charlie Mack
Email- charliemack@irc-us.com

2. Device :

Trade/proprietary name: Piezo Bone Surgery, Model Ultrasurgery
Common Name : Drill, bone, powered
Classification Name : Bone cutting instrument and accessories

3. Predicate Devices :

MECTRON, Piezo Bone Surgery, Piezosurgery, K091227

4. Classifications Names & Citations :

21CFR 872.4120, DZI, Drill, Bone, Powered, Class2

Description :

5.1 General

The Guilin Woodpecker Medical Instrument Co., Ltd. Piezo Bone Surgery device is a dental device used in oral surgery situations. In this submission, it is intended to be used for bone cutting in oral surgery, removing supra and sub-gingival calculus deposits, stains from teeth, periodontal pocket lavage with simultaneous ultrasonic tip movement, scaling, root planning, and retrograde preparation of root canals.

The device is a hand held ultrasonic surgical device, which is connected via a cord to the control console. The device operates at frequency range of 24 to 29.5 kHz. There are three modes of operation, which are selectable from the control console. The practitioner can select the Bone, Root or Clean modes of operation. Each mode has a different power mode, with the Bone mode giving the most power. Irrigation to the tip is provided and adjustable via the control console. Water flow for the irrigation is provided via a peristaltic pump.

A selection of tips is available for the dental professional to select and use for the specific dental procedure. The available tips are shown in the User's manual and also in the advertisement brochure.

This device is not delivered sterile, but must be sterilized after each use. Instructions for cleaning and sterilization are provided within the User's Manual.

5. Indication for use :

The Piezo Bone Surgery is intended for use in the following dental applications:

- Bone cutting for use in oral surgery
- Removing supra and sub-gingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement

- Scaling and root planning
- Retrograde preparation of root canals

6. Comparison with predicate device :

Guilin Woodpecker Medical Instrument Co., Ltd. believes that the Piezo Bone Surgery device, model Ultrasurgery is substantially equivalent to the Mectron, Piezosurgery® (K091227).

Please see the next two pages for a comprehensive comparison with the predicate device.

Element of comparison	Subject Device	Claimed SE Device
Manufacturer	WOODPECKER	MECTRON
Device name	Piezo Bone Surgery	Piezo Bone Surgery
Device model	Ultrasurgery	Piezosurgery ③
FDA510(K) No.	N/A	K091227
Intended use(s)	The Piezo Bone Surgery is intended for use in the following dental applications: - Bone cutting for use in oral surgery - Removing supra and subgingival calculus deposits and stains from teeth - Periodontal pocket lavage with simultaneous ultrasonic tip movement - Scaling and root planning - Retrograde preparation of root canals	The Piezosurgery 3 is intended for use in the following dental applications: - Bone cutting for use in oral surgery - Removing supra and subgingival calculus deposits and stains from teeth - Periodontal pocket lavage with simultaneous ultrasonic tip movement - Scaling and root planning - Retrograde preparation of root canals
Operation	Using piezoelectric ultrasonic technology to generate mechanical micro vibrations for bone cutting and ultrasonic scaling, with minimal trauma to soft tissue.	Using piezoelectric ultrasonic technology to generate mechanical micro vibrations for bone cutting and ultrasonic scaling, with minimal trauma to soft tissue.
Medium used	Purified water or normal saline	Purified water or normal saline
Tip material	Stainless steel	Stainless steel
Ultrasonic vibration style	Piezoelectric Wafer	Piezoelectric Wafer
Device for intermittent operation	Intermittent Operation 60" ON 10" OFF	Intermittent Operation 60" ON 30" OFF
Working frequency	24KHz~29.5 KHz	From 24 KHz to 36 KHz
Voltage supply	100-120VAC 50/60Hz	100-240 VAC 50/60 Hz
APC circuit protection systems	No hand piece connected Cord interrupted Insert broken or not correctly tightened	No hand piece connected Cord interrupted Insert broken or not correctly tightened
Power Modes	ROOT mode BONE mode	ROOT mode BONE mode IMPL mode
IEC60601-1 Class	Type B Class I	Type B Class I

Device classification using Directive 93/42EEC	Class Ⅱa	Class Ⅱa
Peristaltic pump volume delivery	From 25 to 100 ml / min approx	From 0 to 90 ml / min approx
Fuses	Type 5 x 20 mm 2×T1.0AL 250V	Type 5 x 20 mm 230 VAC 2 X 2 A T
Environmental operating conditions	from +10°C to +40°C Relative humidity from 30% to 70%	from +10°C to +40°C Relative humidity from 30% to 75%
Transport and storage environmental conditions	from -10°C to +50°C Relative humidity from 10% to 90%. Air pressure P: 500hPa/1060hPa	from -10°C to +70°C Relative humidity from 10% to 90%. Air pressure P: 500hPa/1060hPa
Where used	Oral surgery Implantology Periodontal surgery Surgical orthodontics	Oral surgery Implantology Periodontal surgery Surgical orthodontics
Biocompatibility	Complying with ISO10993-1	Complying with ISO10993-1
Weight and Size	3.8KG L×W×H:333×255×167mm	3.2 kg L×W×H:340 X 210 X 150 mm
Clean and disinfection method	Clean and disinfect the surfaces of the casting, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH 7).	Clean and disinfect the surfaces of the casing, the rod, the hand piece-holder, the cords and their connectors using a low fiber release cloth moistened with a detergent solution (pH 6-9) and/or a mild disinfectant with a neutral pH (pH7).
Sterilization method	Maximum temperature of 135°C for a maximum of 20 minutes.	Maximum temperature of 135°C for a maximum of 20 minutes.
Components can be sterilized	Hand piece, Tips, Tip holder, Torque wrench, Pump tube, Cord/peristaltic pump tube connection, Hand piece holder	Hand piece, Inserts, Wrench for tightening the inserts, Tube for the peristaltic pump, Connection for the cord / tube of the peristaltic pump, Rod for supporting the bag, Support for the hand piece

7. Safety and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to EN/ IEC 60601-1[1990] Medical electrical equipment Part 1: General Requirement for safety, IEC60601-1-2, EMC Compatibility, ISO10993-5 Cytotoxicity, ISO10993-10 Cytotoxicity, ISO 10993-1 Biological evaluation of Medical Devices Part-1; ISO 7405:2008 Dentistry –Evaluation of biocompatibility of Medical devices used for dentistry; ISO 13485- Risk Management; ISO 14971, Risk Management of Medical Devices. Performance testing was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Guilin Woodpecker Medical Instrument Co., Ltd. concludes that the Piezo Bone Surgery device, model Ultrasurgery is substantially equivalent to predicate devices as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Guilin Woodpacker Medical Instrument Company, Limited
C/O Mr. Charlie Mack
Principal Engineer
International Regulatory Consultants
77325 Joyce Way
Echo, Oregon 97826

NOV 18 2011

Re: K111290
Trade/Device Name: Piezo Bone Surgery
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI, ELC
Dated: November 6, 2011
Received: November 9, 2011

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use

510(k) Number (if known): K111290

Device Name: Piezo Bone Surgery

Indications For Use:

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Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111290